

Docket Number: 037003-0277847

PATENT APPLICATION

Client Reference: 1998-30-0523VUS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of

ANTONIO GRILLO-LOPEZ

Group Art Unit: 1642

Application No.: 09/762,587

Examiner: Minh Tam B. Davis

Filed: September 6, 2001

Confirmation No.: 5272

For: COMBINATION THERAPIES FOR B-CELL LYMPHOMAS COMPRISING  
ADMINISTRATION OF ANTI-CD20 ANTIBODY

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

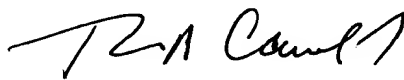
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed with a request for reconsideration. No certification or fee is required.

Respectfully submitted,



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FORM PTO-1449 (modified)  
(PW FORM PAT-1449)



Atty. Ref. No.  
037003-0277847

Client Ref. No.  
1998-30-0523VUS

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**

Applicant: GRILLO-LOPEZ

Appln. No.: 09/762,587

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Page 1 of 4

Examiner: M.T.B. Davis

Group Art Unit: 1642

**U.S. PATENT DOCUMENTS**

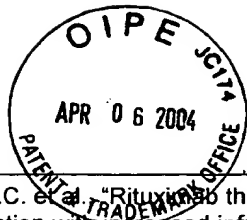
Examiner Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)
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	CR	5,124,471	06/1992	Gansow
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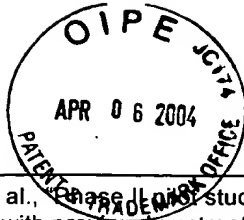
		Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract	Translation Readily Available
	TR	WO87/02671A1	05/1987	PCT	Robinson		
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WR	Anderson, K.C. et al. "Hematologic engraftment and immune reconstitution posttransplantation with anti-B1 purged autologous bone marrow," <i>Blood</i> , 1987, 69(2):597-604.
XR	Azogui, O. et al., "Inhibition of IL 2 production after human allogeneic bone marrow transplantation," <i>J Immunol</i> , 1983, 131:1205-1208.
YR	Berinstein, N.L. et al., "Association of serum Rituximab (IDEC-C2B8) concentration and anti-tumor response in the treatment of recurrent low-grade or follicular non-Hodgkin's lymphoma," <i>Annals of Oncology</i> , 1998, 9(9):995-1001.
ZR	Bosly, A., et al., "Interleukin-2 after autologous bone marrow transplantation as consolidative immunotherapy against minimal residual disease," <i>Nouv Rev Fr Hematol</i> , 1990, 32(1):13-16.



AAR	Byrd, J.C. et al., "Rituximab therapy in hematologic malignancy patients with circulating blood tumor cells: Association with increased infusion-related side effects and rapid tumor lysis," <i>Blood</i> , 1998, 92(10):106a, abstract #432.
BBR	Byrd, J.C. et al., "Rituximab therapy in previously treated Waldenstrom's Macroglobulinemia: Preliminary evidence of activity," <i>Blood</i> , 1998, 92(10):106(a), abstract #433.
CCR	Caligiuri, M.A. et al., "Extended continuous infusion low-dose recombinant Interleukin-2 in advanced cancer. Prolonged immunomodulation without significant toxicity," <i>J Clin Oncol</i> , 1991, 9(12):2110-2119.
DDR	Caligiuri, M.A. et al., "Selective modulation of human natural killer cells in vivo after prolonged infusion of low dose recombinant Interleukin 2," <i>J Clin Invest</i> , 1993, 91(1):123-132.
EER	Caligiuri, M.A., "Low-dose recombinant Interleukin-2 therapy: rationale and potential clinical applications," <i>Semin Oncol</i> , 1993, 20(6 suppl 9):3-10.
FFR	Cayeux, S. et al., "T-cell ontogeny after autologous bone marrow transplantation: failure to synthesize Interleukin-2 (IL-2) and lack of CD2- and CD3-mediated proliferation by both CD4+ and CD8+ cells even in the presence of exogenous IL-2," <i>Blood</i> , 1989, 74(6):2270-2277.
GGR	Czuczman, M.S. et al., "Treatment of patients with low-grade B-cell lymphoma with the combination of chimeric anti-CD20 monoclonal antibody and CHOP chemotherapy," <i>Journal of Clinical Oncology</i> , 1999, 17(1):268-276.
HHR	Czuczman, M.S. et al., "Rituximab/CHOP chemioimmunotherapy in patients (PTS) with low grade lymphoma (LG/F NHL): progression free survival (PFS) after three years (median) follow-up," <i>Blood</i> , 1999, 94(1):99a, abstract 432.
IIR	Davis, T.A. et al., "Retreatments with Rituxan (Rituximab, IDEC-C2B8) have significant efficacy, do not cause hama, and are a viable minimally toxic alternative in relapsed or refractory non-Hodgkin's lymphoma (NHL)," <i>Blood</i> , 1997, 90(10):509A, abstract #2269.
JJR	Davis, T.A. et al., "Therapy of B cell lymphoma with anti-CD20 antibodies can result in the loss of CD20 antigen expression," <i>Clinical Cancer Research</i> , 1999, 5(3):611-615.
KKR	Davis, T. et al., "Combination immunotherapy of low grade or follicular (LG/F) non-Hodgkin's lymphoma (NHL) with Rituximab and alpha interferon: interim analysis," <i>Proceedings of the American Society of Clinical Oncology</i> , 1998 17: 11a, abstract #39.
LLR	Davis, T. et al., "Rituximab: Phase II (PII) 1, 2, 5, retreatment (ReRx) study in patients (PTS) 15-17 with low-grade or follicular (LG/F) NHL," <i>Blood</i> , 1998, 92(10 Suppl 1): 414a, abstract #1710.
MMR	Demidem, A. et al., "Chimeric anti-CD20 (IDEC-C2B8) monoclonal antibody sensitizes a B cell lymphoma cell line to cell killing by cytotoxic drugs," <i>Cancer Biotherapy &amp; Radiopharmaceuticals</i> , 1997, 12(3):177-186.
NNR	Dillman, R.O., "Antibodies as cytotoxic therapy," <i>Journal of Clinical Oncology</i> , 1994, 12(7):1497-1515.
OOR	Flinn, I.W. et al., "In vivo purging and adjuvant immunotherapy with Rituximab during PBSC transplant for NHM," <i>Blood</i> , 1998, 92(10 Suppl 1):648a, abstract #2673.
PPR	Greiner, J.W. et al., "Recombinant interferon enhances monoclonal antibody-targeting of carcinoma lesions in vivo," <i>Science</i> , 1987, 235(4791):895-898.
QQR	Grillo-López, A., "Treatment options for patients with relapsed low-grade or follicular lymphoma: The role of IDEC-C2B8," <i>Tenth International Conference on Monoclonal Antibody Immunoconjugates for Cancer</i> , March 9-11, 1995, 8:60, abstract #10.
RRR	Grossbard, M., et al., "Monoclonal antibody-based therapies of leukemia and lymphoma," <i>Blood</i> , 1992, 80(4):863-878.
SSR	Hagenbeek, A., et al., "Maintenance of remission with human recombinant interferon alfa-2a in patients with stages III and IV low-grade malignant non-Hodgkin's lymphoma," for European Organization for Research and Treatment of Cancer Lymphoma Cooperative Group, <i>Journal of Clinical Oncology</i> , 1998, 16(1):41-47.
TTR	Horning, S.J. et al., "Rituximab treatment failures: tositumomab and iodine I-131 tositumomab [Bexxar®] can produce meaningful durable responses," <i>Blood</i> , 2002, 100(11):357a, abstract #1385.
UUR	Janakiraman, N. et al., "Rituximab: correlation between effector cells and clinical activity in NHL," <i>Blood</i> , 1998, 92(10):337a, abstract #1384.
VVR	Klarnet, J.P. et al., "Antigen-driven T cell clones can proliferate in vivo, eradicate disseminated leukemia, and provide specific immunologic memory," <i>J Immunol</i> , 1987, 138(11):4012-4017.
WWR	Knox, S.J. et al., "Yttrium-90-labeled anti-CD20 monoclonal antibody therapy of recurrent B-cell lymphoma," <i>Clinical Cancer Research, The American Association for Cancer Research</i> , 1996, 2(3):457-470.
XXR	Kuzel, T. et al., "A phase I escalating-dose safety, dosimetry and efficacy study of radiolabeled monoclonal antibody LYM-1," <i>Cancer Biotherapy</i> , 1993, 8(1):3-16.
YYR	Lauria, F. et al., "Immunologic and clinical modifications following low-dose subcutaneous administration of rIL-2 in non-Hodgkin's lymphoma patients after autologous bone marrow transplantation," <i>BMT</i> , 1996, 18(1):79-85.



ZZR	Link, B., et al., "Phase I clinical trial study of the safety and efficacy of rituximab in combination with CHOP chemotherapy in patients with previously untreated intermediate- or high-grade NHL," <i>Proceedings of the American Society of Clinical Oncology</i> , 1998, 17:3a, No. 7.
AAAR	Lum, L.G. et al., "The kinetics of immune reconstitution after human marrow transplantation," <i>Blood</i> , 1987, 69(2):369-380.
BBBR	Maloney, D.G. et al., "Phase I clinical trial using escalating single-dose infusion of chimeric anti-CD20 monoclonal antibody (IDEC-C2B8) in patients with recurrent B-cell lymphoma," <i>Blood</i> , 1994, 84(8):2457-2466.
CCCR	Maloney, D.G. et al., "IDEC-C28B: Results of a phase I multiple-dose trial in patients with relapsed non-Hodgkin's lymphoma," <i>J Clin Oncol</i> , 1997, 15(10):3266-3274.
DDDR	McLaughlin, P. et al., "Efficacy controls and long-term follow-up of patients (PTS) treated with rituximab for relapsed or refractory, low-grade or follicular NHL," <i>Blood</i> , 1998, 92(10):414a-415a, abstract #1712.
EEER	Murray, J. et al., "Recombinant alpha-interferon enhances tumor targeting of an antimelanoma monoclonal antibody in vivo," <i>Journal of Biological Response Modifiers</i> , 1990, 9(6):556-563.
FFFR	Nakamura, K. et al., "Effect of alpha-interferon on anti-alpha-fetoprotein-monoclonal-antibody targeting of hepatoma," <i>Oncology</i> , 1993, 50(1):35-40.
GGGR	O'Brien, S. et al., "Lack of effect of 2-chlorodeoxyadenosine therapy in patients with chronic lymphocytic leukemia refractory to fludarabine therapy," <i>N Engl J Med</i> , 1994, 330(5): 319-322.
HHHR	O'Brien, S. et al., "Phase I/II Study of Rituxan in chronic lymphocytic leukemia (CLL)," <i>Blood</i> , 1998, 92:105a, abstract #431.
IIIR	Pietersz, G.A. et al., "The Use of monoclonal antibody conjugates for the diagnosis and treatment of cancer," <i>Immunol Cell Biol</i> , 1987, 65(pt 2):111-125.
JJJR	Press, O. et al., "Monoclonal antibody 1F5 (anti-CD20) serotherapy of human B cell lymphomas," <i>Blood</i> , 1987, 69(2):584-591.
KKKR	Press, O.W., et al., "Prospects for the management of non-Hodgkin's lymphomas with monoclonal antibodies and immunoconjugates," <i>Cancer-Journal from Scientific American, Scientific American, Inc</i> , 1998, 4(2):S19-S26.
LLLR	Press, O., et al., "A phase I/II trial of high dose iodine-131-anti-B1 (anti-CD20) monoclonal antibody, etoposide, cyclophosphamide, and autologous stem cell transplantation for patients with relapsed B cell lymphomas," <i>Proc Annu Meet Am Soc Clin Oncol</i> , 1998, 17 A9.
MMMR	Reff, M. et al., "Depletion of B cells in vivo by a chimeric mouse human monoclonal antibody to CD20," <i>Blood</i> , 1994, 83(2):435-445.
NNNR	Shipp et al., "The International Non-Hodgkin's Lymphoma Prognostic Factors Project: A predictive model for aggressive non-Hodgkin's lymphoma," <i>New England J Med</i> , 1993, 329(14):987-994.
OOOR	Smalley, R. et al., "Interferon alpha combined with cytotoxic chemotherapy for patients with non-Hodgkin's lymphoma," <i>New England Journal of Medicine</i> , 1992, 327(19):1336-1341.
PPPR	Soiffer, R.J. et al., "Clinical and immunologic effects of prolonged infusion of low- dose recombinant Interleukin-2 after autologous and T-cell-depleted allogeneic bone marrow transplantation," <i>Blood</i> , 1992, 79(2):517-526.
QQQR	Soiffer, R.J. et al., "Effect of low-dose Interleukin-2 on disease relapse after T-cell-depleted allogeneic bone marrow transplantation," <i>Blood</i> , 1994, 84(3):964-971.
RRRR	Solal-Céligny, P. et al., "Doxorubicin-containing regimen with or without interferon alfa-2b for advanced follicular lymphomas: final analysis of survival and toxicity in the Groupe d'Etude des Lymphomes Folliculaires 86 Trial," <i>Journal of Clinical Oncology</i> , 1998, 16(7):2332-2338.
SSSR	Tobinai, K. et al., "Feasibility and pharmacokinetic study of a chimeric anti-CD20 monoclonal antibody (IDEC C2B8, rituximab) in relapsed B-cell lymphoma," <i>Annals of Oncology</i> , 1998, 9(5):527-534.
TTTR	Tsai, D. et al., "Progressive intermediate grade non-Hodgkin's lymphoma after high dose therapy and autologous peripheral stem cell transplantation (PSCT) has a high response rate to Rituximab," <i>Blood</i> , 1998, 92(10):415a, abstract #1713.
UUUR	Van der Kolk, L.E. et al., "Chimeric anti-CD20 monoclonal antibody (rituximab) plus G-CSF in relapsed B-cell lymphoma: A phase I/II clinical trial," <i>Blood</i> , 1998, 92(10 Suppl 1):241b, abstract #4037.
VVVR	Van der Kolk, L.E. et al., "Chimeric anti-CD20 monoclonal antibody (rituximab) plus G-CSF in relapsed B-cell lymphoma: A phase I/II clinical trial," <i>British Journal of Haematology</i> , 1998, 102(1):243 [Combined Haematology Congress of the International Society of Haematology and the European Hematology Association, Amsterdam, Netherlands, July 4-8, 1998].
WWWR	Venugopal, P. et al., "Upregulation of CD20 expression in chronic lymphocytic leukemia (CLL) cells by <i>in vitro</i> exposure to cytokines," <i>Blood</i> , 1998, 92(10):247a, abstract #1009.
XXXR	Vey, N. et al., "A pilot study of autologous bone marrow transplantation followed by recombinant Interleukin-2 in malignant lymphomas," <i>Leukemia &amp; Lymphoma</i> , 1996, 21(1-2):107-114.



YYYYR	Wadler S, et al., Principles and Practice of the Modulation of cytotoxic drugs by interferons," <i>Seminars in Oncology</i> , 1992, 19(2 suppl 3):45-48.
ZZZR	Wahl, R.L. et al., "Successful re-treatment of non-Hodgkin's lymphoma (NHL) with iodine-131 anti-B1 antibody (Meeting abstract)," <i>Proc Annu Meet Am Soc Clin Oncol</i> , May 1998, 17:40a, abstract #156.
AAAAR	Welte, K. et al, "Defective Interleukin 2 production in patients after bone marrow transplantation and in vitro restoration of defective T lymphocyte proliferation by highly purified Interleukin 2," <i>Blood</i> , 1984, 64:380-5.
BBBBR	Winkler, U., et al., Severe side effects in patients with B-cell chronic lymphocytic leukemia (CLL) and lymphocytosis treated with the monoclonal anti-CD20 antibody Rituximab," <i>Blood</i> , 1998, 92(10):285b, abstract #4228.
CCCCR	Wiseman, O., et al., IDEC-Y2B8 radioimmunotherapy: Baseline bone marrow involvement and platelet count are better predictors of hematologic toxicity than dosimetry. <i>Blood</i> , 1998, 92(10):417a, abstract #1721.
DDDDR	Witherspoon, R.P. et al., "Immunologic reconstitution after human marrow grafting," <i>Semin Hematol</i> , 1984, 21(1):2-10.
EEEEER	Witzig, T. et al., "IDEC-Y2B8 Radioimmunotherapy: Responses in patients with splenomegaly," <i>Blood</i> , 1998, 92(10):417(a), #1722.
FFFFR	Witzig, T.E. et al., "Phase I/II trial of IDEC-Y2B8 radioimmunotherapy for treatment of relapsed or refractory CD20+ B-cell non-Hodgkin's lymphoma," <i>J Clin Oncol</i> , 1999, 17(12): 3793-3803.
GGGGR	Yokota, S. et al., "Synergistic potentiation of in vivo antitumor activity of anti-human T-leukemia immunotoxins by recombinant alpha-interferon and daunorubicin," <i>Cancer Research</i> , 1990, 50:32-37.

Examiner	Date Considered:
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	